Remarks

Claims 1-22 and 137 are pending. Applicants elected to prosecute the invention of Group I - claims 1-22 and 137, drawn to a method of making dosage forms. Claims 23-136 have been canceled without prejudice to the filing of claims directed to the canceled subject matter in this or a related application. Claims 1 and 21 have been amended to refer to a "dosage form per se", which is described on pages 12, 27 and 32. The phrase "per se" means "by, of, or in itself or oneself or themselves." Merriam-Webster's Collegiate Dictionary, 10th Edition. No new matter has been added.

The Examiner rejects claims 1, 6-10 and 137 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,830,502 ("Dong et al."). The Examiner asserts that the reference teaches the claimed process for manufacturing an injection molded dosage form. Applicants respectfully traverse this rejection.

Claim 1 is directed to a method of making a dosage form containing a first medicant. The process requires the steps of injecting through a nozzle a **flowable material containing said first medicant** into a mold cavity and hardening said flowable material into a molded dosage form per se having a shape substantially the same as the mold cavity. The flowable material injected into the mold cavity must contain at least one medicant. Applicants reiterate that the dosage forms contemplated by Dong do not satisfy all of these requirements.

The Examiner argues that the compositions of Dong contain a medicament and that the claims are broad enough to read on the process shown in Dong. The Examiner refers to column 5, lines 63-67, which provides that "more than one therapeutic agent can be incorporated into the dosage form..." and column 6, lines 15-20, which provides for specific dosage amounts. As noted above, the claims provide that a dosage form per se is formed by the molding process, not a combination of a molded housing into which active ingredients are subsequently introduced. While therapeutic agents are shown in Dong, these agents are not in the flowable material used in the molding process. Hence, Dong fails to anticipate the claimed inventions herein.

Dong describes a process for making an osmotic device having an injection molded housing member. The molding compositions contain "thermoplastic polymer, or copolymer, or the compositions comprise a mixture of thermoplastic polymers and optional injection-molding ingredients." Col. 3, lines 8-10. Subsequently, Dong teaches that the compositions

can comprise 100% thermoplastic polymer or a blend of polymers, "with all polymers equal to 100%." Col. 3, line 44. Contrary to the Examiner's allegation, there is absolutely no suggestion that the molding compositions of Dong could contain a medicament.

The therapeutic agent is taught as being made in conventional manner. One embodiment presses the therapeutic agent into a solid shape that can be pressed into the internal dimensions of the dosage form. A second embodiment presses the therapeutic agent into a layer for incorporation into the dosage form. See passage in column 4, lines 39-55. The incorporation of a medicament in an outer molded shell would not be consistent with the primary purpose of an osmotic device, which is precise delivery of medicament through an opening using an osmagent and push composition. Hence, Dong fails to disclose at least one material feature of the claimed process - the presence of at least one medicament in the flowable material.

Claim 10 provides that the flowable material comprises gelatin. The specification notes that gelatin is an extremely different material to use as an injection molded material for making dosage forms. Gelatins, once hydrated, have a very abrupt transition temperature between the liquid and solid/gel phases. See publication of instant application, US 2003/0086973 A1, paragraph 173. Gelatins are fundamentally different from thermoplastics in this regard. Consequently, it has not been known for such use in this field.

Dong describes the use of:

"synthetic resins, for example, linear polycondensation resins, condensation polymerized resins, addition polymerized resins, such as polyamides, resins obtained from diepoxides and primary alkanolamines, resins of glycerine and phthalic anhydrides, polyvinyl resins, polymer resins with end-positions free or esterified carboxyl or carboxamide groups, for example with acrylic acid, acrylic amide, or acrylic acid esters, polycaprolactone, and its copolymers with dilactide, diglycolide, valerolactone and decalactone, a resin composition comprising polycaprolactone and polyalkylene oxide, composition comprising polycaprolactone and a polyalkylene oxide such as polyethylene oxide, cellulose such as hydroxypropylmethylcellulose, hydroxyethylmethylcellulose, hydroxyethylcellulose, and hydroxypropylcellulose, copoly(butylene terephthalate-tetrahydrofuran), copoly(alkylene oxide-methylmethacrylate), and ethylene vinylacetate copolymer.

None of the exemplified resins contemplate a gelatin or gelatin-like material.

The Examiner asserts that gelatin is suggested for use as a push layer at column 7, line 30 in Dong. Applicants do not dispute this point. The push layer in Dong, however, is not a molded member of the dosage form. The push layer of Dong is not formed by injecting a flowable material (gelatin as to claim 10) into a mold cavity. Hence, Dong fails to disclose or suggest the use of gelatin as required by claim 10. For all of the above reasons, Applicants request that the Examiner reconsider and withdraw her anticipation rejection of claims 1, 6-10, and 137 in view of Dong.

The Examiner rejects claims 1-5, 11-13, 21 and 137 under 35 U.S.C. 103 as being unpatentable over Dong. Applicants respectfully traverse this rejection.

Dong does not disclose or suggest having a first medicament in the flowable material used to make the molded dosage form per se. A medicament is not a proposed or even contemplated optional constituent of the molding compositions for the housing member. Dong does not disclose or suggest a process for molding a dosage form per se erein gelatin is part of the flowable material. Applicants submit that the Examiner has failed to establish a prima-facie showing of obviousness of the inventions recited in claims 1-5, 11-13, 21 and 137. Applicants request that the Examiner reconsider and withdraw her obviousness rejection in view of Dong.

The Examiner rejects claims 14-20, 22 and 137 under 35 U.S.C. 103 as being unpatentable over Dong in view of U.S. Patent No. 6,177,125 ("Voss et al."). Dong is applied as described above. The Examiner cites Voss as teaching the addition of core or insert in the mold prior to complete molding of the tablet. Applicants respectfully traverse this rejection.

As noted immediately above, Dong does not disclose or suggest having a first medicament in the flowable material used to make the molded dosage form per se. Dong does not disclose or suggest a process for molding a dosage form wherein gelatin is part of the flowable material. Voss does not disclose an injection molding process, nor does Voss describe the use of gelatin material. Voss does not disclose either of these material features of the claimed process, which are lacking in Dong. Assuming the references can be combined, the resulting process does not disclose or suggest the claimed molding process for manufacturing dosage forms. Applicants request that the Examiner reconsider and withdraw her obviousness rejection in view of Dong and Voss.

Applicants submit that the present application is now in condition for allowance. Applicants request that the Examiner contact the undersigned representative if minor amendments will further prosecution towards issuance.

Respectfully submitted,

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